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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/718,155	11/20/2003	Christopher J. Moran	3433-483	9003

7590 12/28/2009

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EXAMINER	
BUI, VY Q	

ART UNIT	PAPER NUMBER
3773	

MAIL DATE	DELIVERY MODE
12/28/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/718,155	MORAN ET AL.	
	Examiner	Art Unit	
	Vy Q. Bui	3773	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *15 September 2009*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *27-37 and 40-67* is/are pending in the application.

4a) Of the above claim(s) *28,30,34,36,51-54,59,60 and 63-67* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *27,29,31-33, 35, 37, 40-50, 55-58, 61-62* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

A review of the prosecution of the case reveals a comminuted form of material for the device was elected (paper 3/23/2007) for further examination in this present invention. A different election of the species for examination, such as a coil as shown in Fig. 8-9, will shift the focus on another non-elected species and will lengthen the prosecution of the present application.

Therefore, claims 28 and 34 (coil device), claims 30, 36, 51-54 (submucosa sheet), claims 59-60, 63, 67 (metallic backbone) and claims 64-66 (helical component) have been withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention.

Election was made **without** traverse in the reply filed on 3/23/2007.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 32, 37, 41-43, 45-46 are rejected under 35 U.S.C. 102(b) as anticipated by Ritchart et al.- 4,994,069.

As to claims 32, 37, 42-43, 45-46, Ritchart-'069 (F. 10; C 1, L 25-52; C 3, L 42-49) discloses an embolization device as an injectable fluid or gel, such as a microfibrillar collagen (C 1, L 30-43) and especially a drug-contained collagen bolus 74 as an occluding device, which is injected by device 12 (F 10; C 4, L 26-28) to cause a full occlusion and full blockage in a blood vessel.

As to claim 41, Ritchart-'069 also discloses radio contrast material (C 1, L 45-48) is mixed in an injectable gel for fluoroscopic viewing.

Note that by nature, collagen is an extracellular protein matrix in skin, bone, cartilage, tendon, teeth to form strong insoluble fibers and to serve as connective tissue between cells.

Claim Rejections - 35 USC § 103

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

1. Claims 27, 29, 31, 33, 35, 40 and 44 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ritchart et al.- 4,994,069 in view of Badylak et al.-5,275,826.

As to claims 27, 29, 31, 33, 35, 40 and 44, Ritchart-'069 discloses substantially the claimed invention, except for the injectable embolization fluid or gel comprising a submucosa. However, Badylak-'826 (abstract, for example) discloses comminuted submucosa in an injectable fluid or gel suitable for injection into a warm blooded body as a matrix for a regrowth of the local tissue (C 1, L 16-39). It would have been obvious to one of ordinary skill in the art to replace the injectable fluid or gel of Ritchart-'069 with injectable fluid or gel of submucosa as taught by Badylak-'826, as this configuration would provide a matrix for a regrowth of the local tissue and therefore promote a natural local occlusion of a treatment site.

2. Claims 47-48, 50, 55-58, 61-62 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ritchart et al.- 4,994,069 in view of Badylak et al.-5,275,826 and further in view of Boock et al.-6,187,024 B1.

As to claims 47-48, 50, 55-58, 61-62, as indicated in 103(a) rejection item 1 above, Ritchart-'069 and Badylak-'826 discloses substantially the claimed invention, except for a biotropic agent such as a growth factor as recited in the claims. However, Boock-'024 (for example: F. 1, 3; C 3, L 32-44) discloses an embolization device 100 having an outer coating of a proteinacious, preferably collageneous material in nature mixed with a growth factor to promote a local tissue growth. It would have been obvious to one of ordinary skill in the art to provide a growth factor to the embolization device to promote a local tissue growth to more effectively occlude the local site.

As to claim 49, amniotic is a well known material for an implant into a patient body because amniotic is a natural biocompatible material. It would have been obvious to one of ordinary skill in the art to replace a natural biocompatible collagen material or a natural biocompatible submucosa material for an amniotic material as amniotic material is also a natural biocompatible suitable for an implant in a body.

Note that an embolization device is well known for filling an aneurysm to fully occlude the aneurysm to prevent any further expansion of the aneurysm inside a body.

Response to Arguments

Applicant's arguments filed 9/15/09 have been fully considered but they are not persuasive because the claims as recited do not exclude the case that the embolization device includes a coil.

Further, collagen bolus 74 (Ritchart-'069: F 10; C 4, L 26-28) is indeed all-natural blockage remains fully occluding a blood vessel for a period of time.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Vy Q. Bui whose telephone number is 571-272-4692. The examiner can normally be reached on Monday-Tuesday and Thursday-Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jackie Ho can be reached on 571-272-4696. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Vy Q. Bui/
Primary Examiner, Art Unit 3773